

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 02419
LITIGATION)	Docket No. 1:13-md-2419-RWZ
_____)	
)	
This document relates to:)	
)	
Handy v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14019-RWZ)	
)	
Armetta v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14022-RWZ)	
)	
Torbeck v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14023-RWZ)	
)	
Kashi v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14026-RWZ)	
)	
Bowman v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14028-RWZ)	
)	
Dreisch v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14029-RWZ)	
)	
Davis v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14033-RWZ)	
)	
Farthing v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14036-RWZ)	

BOX HILL DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT
CONCERNING PLAINTIFFS' CLAIM FOR RECOVERY OF MEDICAL EXPENSES

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively “Defendants,” “Box Hill Defendants,” or “Box Hill”), by undersigned counsel, submit this memorandum of law in support of their Motion For

Summary Judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure and the authority cited below.

I. INTRODUCTION

In each of the above captioned cases, Plaintiffs have asserted a damages claim for medical expenses incurred as a result of the Box Hill Defendants' alleged negligence.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which otherwise do not apply to the singular claim addressed in this motion for summary judgment.

This action is among hundreds, if not thousands, of lawsuits across the United States arising out of the administration of a steroid—preservative free methylprednisolone acetate (hereinafter “MPA”)—manufactured, contaminated, and distributed by New England Compounding Pharmacy, Inc. a/k/a New England Compounding Center (hereinafter “NECC”), a now dissolved corporation in Massachusetts. NECC provided MPA for purchase nationally to many physicians, ambulatory surgery centers, clinics, and hospitals, including Defendant Box Hill Surgery Center, which is an ambulatory surgery center solely owned by Defendant Bhambhani. It is alleged that as a result of negligent manufacturing, cleaning and sterilization practices by NECC, as well as improper testing and “clean-room” design, that certain vials or batches of MPA became contaminated with fungus in 2012 and may have caused varying levels of harm or injury to patients, who had received the MPA from their health care providers. It is alleged that the contaminated vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102012@51 (BUD 2/6/2013).

The MPA in the recalled lots was shipped to health care providers, including the Box Hill Defendants, who administered the drugs to patients before it was discovered that the lots were

contaminated. These lots were recalled by NECC under pressure from the CDC on or about September 26, 2012, but not until after numerous patients fell ill, and some died, after developing fungal meningitis or other neurologic or infectious process. Plaintiffs' claims for damages includes medical expenses incurred as a result of the alleged negligence of the Box Hill Defendants.

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment as to Plaintiffs' claims for medical expenses that were in excess of the amount that Plaintiffs, or someone on Plaintiffs' behalf, have paid or are obligated to pay.

II. STATEMENT OF FACTS¹

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").²

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).³

3. The Plaintiffs' claims against the Box Hill Defendants arise from alleged injuries suffered from potential exposure to MPA administered by Dr. Bhambhani and the Box Hill Defendants while performing epidural steroid injection procedures.⁴

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.⁵

¹ The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.

² Dreisch Complaint at 3, ¶ 1.

³ Dreisch Complaint at 17, ¶ 51.

⁴ Dreisch Complaint at 37, ¶ 145.

⁵ See Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center (“NECC”) even in just the five months preceding the meningitis outbreak at issue.⁶

6. NECC was regulated and inspected by the U.S. Food and Drug Administration (“FDA”).⁷ In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that “the Federal Food, Drug, and Cosmetic Act (“FDCA”) establishe[d] agency jurisdiction over ‘new drugs,’ including compounded drugs.”⁸

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Womens Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.⁹

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to “follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure,” failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce “sterile” drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.¹⁰

⁶ See NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.

⁷ See FDA Warning Letter, attached as **Exhibit 3**.

⁸ *Id.*

⁹ See Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women’s Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women’s Vendor Audit Survey Form, attached as **Exhibit 6**.

¹⁰ Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64.

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.¹¹

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.¹² As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.¹³

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.¹⁴

12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.¹⁵

13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.¹⁶ Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.¹⁷

¹¹ See Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; see also Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

¹² *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

¹³ Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

¹⁴ See Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

¹⁵ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

¹⁶ See Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.

¹⁷ See *id.*

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.¹⁸

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.¹⁹

III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is "entitled to judgment as a matter of law" when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id.* at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id.* at 324. To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth "specific facts showing there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

IV. LEGAL ARGUMENT

Maryland law is well-settled that recoverable medical expenses in healthcare liability actions are limited to those that are necessary and reasonably related to the alleged negligence, and

¹⁸ See *id.*, 64:7–65:1, excerpts attached as **Exhibit 7**.

¹⁹ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

paid or payable by the plaintiffs or third-party payors. Plaintiffs are not permitted to recover the gross amount of charges because such an amount fails to take into account contractual adjustments or write-offs. Thus, this Court should limit Plaintiffs' claim for damages relating to medical expenses to those expenses that the Plaintiffs, or individuals on Plaintiffs' behalf, have paid or are obligated to pay.

Section 3-2A-09(d)(1) of the Courts & Judicial Proceedings Article establishes that a verdict for past medical expenses *shall* be limited to (i) the total amount of past medical expenses paid by or on behalf of the plaintiff and (ii) the total amount of past medical expenses incurred but not paid by or on behalf of the plaintiff for which the plaintiff or another person on behalf of the plaintiff is obligated to pay.

The Maryland Court of Appeals has ruled that write-offs and discounts by health care providers should be considered by a court and a verdict reduced accordingly pursuant to Section 3-2A-09(d)(1). *See Lockskin v. Semsker*, 412 Md. 257, 287 (2010). The plain language of the statute mandates that amounts written-off and discounted by health care providers shall not be included in the amount Plaintiffs are permitted to recover. *Id.* at 286. Seeking medical expenses more than Plaintiffs are entitled to recover, therefore, serves only to prejudice the Defendants and not for any relevant or probative value. When the prejudice of potential evidence outweighs the probative value, then it should be deemed inadmissible. Md. Rule 5-403; F.R.E. 403.

Accordingly, Plaintiffs' attempt to recover any amount in excess of past medical expenses *paid* by or on behalf of the Plaintiffs is irreconcilable with established statutory framework and should be precluded as a matter of law.

V. CONCLUSION

For the foregoing reasons, the Box Hill Defendants respectfully request that the Court grant its motion for summary judgment to limit Plaintiffs' claim for damages related to medical expenses as outlined above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2017, I served the above Motion and attached Memorandum of Law upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

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